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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,507	12/01/2004	Martin Loessner	05146.0003U2	5123

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EXAMINER	
SINGH, SATYENDRA K	
ART UNIT	**PAPER NUMBER**
1657	

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10/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,507	LOESSNER ET AL.	
	Examiner	Art Unit	
	Satyendra K. Singh	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-66 and 69* is/are pending in the application.

4a) Of the above claim(s) *67,68 and 70-95* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-66 and 69* is/are rejected.

7)☒ Claim(s) *50* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/01/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed with the office on February 16th 2007 is duly acknowledged.

Claims 49-66 and 69 (applicant's elected group I) are examined on their merits in this office action.

Claims 67, 68 and 70-95 (non-elected groups II-V) are withdrawn from further consideration.

Election/Restrictions

Applicant's election with traverse of group I (claims 49-66 and 69; drawn to a composition comprising phage P100 and method of using said composition for controlling *Listeria* contamination) in the reply filed on February 16th 2007 is acknowledged. The traversal is on the ground(s) that:

> "all of the claims of at least Groups I, II and III relate to the special technical feature phage P 100, while Groups IV and V relate to a protein derived from phage P 100. MPEP 1850 states that "[w]hether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step."

This is not found persuasive because groups (I-V) as claimed are drawn to multiple inventions that are directed to multiple products (a composition comprising phage P100 versus a purified endolysin protein) and methods of using each said products, thus lacking the unity of invention. For example, the invention of groups I, II and III are directed to three distinct processes, comprising distinct method steps, components used, and resulting in distinct end points. The method of group II requires the method step of administering an amount of said composition to an animal infected with *Listeria monocytogenes*, whereas, the invention of group I requires applying said

composition to a food product or food processing equipment. Similarly, the invention of group III requires distinct method steps (such as obtaining a sample suspected to contain *Listeria monocytogenes*; incubating said sample with said composition; detecting any changes in said sample), which are not required by the inventions of groups I and II, as claimed. Furthermore, the inventions of group IV and V are drawn to a distinct product composition (a purified endolysin protein derived from phage P100), and a method of use, which require distinct components and method steps, and thus lack unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims Suggestions

1. Claims 51, 61 and 65 recite the biological name of a microorganism (*Listeria monocytogenes*) that should be properly italicized.

Claim Objections

1. Claim 50 is objected to because of the following informalities: claim recites "**51**." at the end in line 2 of the claim (presumed typographical error), which should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 49-66 and 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to enable one skilled in the art to which it pertains, or with which it is most connected, to make and/or use the invention.

The invention appears to employ novel biological materials, virulent/lytic phage P100 (ATCC deposit designation no. PTA-4383) and virulent/lytic phage A511 (ATCC deposit designation no. PTA-4608). Since the biological materials are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological material is not so obtainable or available, the requirements of 35 U.S.C. §112 may be satisfied by a deposit of the biological material. The specification does not disclose a repeatable process to obtain the biological material and it is not apparent if the biological material is readily available to the public.

It is noted that applicant has deposited the biological material (instant specification, pages 2a and 3, in particular, or published application, US 2005/0175594 A1, paragraph [0006], in particular), but there is no indication in the specification as to **public availability**. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological material (in the instant case, the virulent/lytic phages P100 and A511, as cited in the instant claims) has been **deposited under the Budapest Treaty and that the biological material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent**, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit

meets the criteria set forth in 37 C.F.R. §1.801-1.809, applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. §1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. § 2400 in general, and specifically to § 2411.05, as well as to 37 C.F.R. §1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination". The specification should be amended to include this information, however, applicant is cautioned to avoid the entry of new matter into the specification by adding any other information.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 57 and 62 recite the limitation "**said food storage container**" or "said food storage containers", respectively. There is insufficient antecedent basis for this limitation in the claims. The broader claim 49 (from which claims 57 and 62 depend from) recites the method step of "applying lytic phage P100....to a food product or food processing equipment", and therefore, the recitation of "said food storage container(s)" is deemed improper. Appropriate explanation/correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 63-66 and 69 are rejected as being directed to a non-statutory subject matter (i.e. a product of nature).

> The claims are directed to a composition comprising phage P100 (ATCC patent deposit designation number PTA-4383) and a carrier; said composition further comprising phage A511 (ATCC patent deposit designation number PTA-4608); the composition further comprising "an agent selected from the group consisting of listeriolysin, ...an enzyme, ...a phage specific for bacterial contaminants other than *Listeria monocytogenes*"; wherein said carrier is a pharmaceutically acceptable carrier; and Phage P100 (deposited at the American Type Culture Collection, ATCC patent deposit designation number PTA-4383).

The invention as claimed, reads on the natural products, (i.e. phage P100 alone and in combination with phage A511, or other phage) that are substantially unaltered, and encompass compositions of food products (for example, cheese, dairy products, etc.) that are found contaminated with pathogenic bacteria such as *Listeria monocytogenes* (and/or other bacterial contaminants).

The invention, as recited, does not provide any structural distinction in the product as claimed, and the product resulting from bacterial contamination of food or

dairy products commonly occurring in nature. Appropriate explanation/correction is required.

> *As per MPEP 706.03(a) [R-5] B. Naturally Occurring Article "Similarly, **a thing occurring in nature**, which is substantially unaltered, is not a "manufacture." A shrimp with the head and digestive tract removed is an example. Ex parte Grayson, 51 USPQ 413 (Bd. App. 1941)."*

Claim Rejections - 35 USC § 102/103(a)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 63, 64, 66 and 69 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Loessner & Busse (1990; [U]) or Loessner et al (1996; IDS).

The claims are drawn to a bacteriophage (P100 alone and in combination with another virulent phage A511), which produces lysis of bacterial host, *Listeria monocytogenes* that contaminate various food, dairy products, and processing equipments.

The cited references discloses phage A511 (see, e.g., Loessner & Busse, abstract, page 1914, table 2, results, *Bacteriophages*, in particular; see also disclosure from Loessner et al, 1996, page 1133, right column and page 1134, left column, section on *Homologous recombination*, in particular), which appear to be identical to the presently claimed strain since it produces same lysis or lytic phenotype on the bacterium, *Listeria monocytogenes*. The referenced microorganism appears to be identical to the presently claimed phage P100 and is considered to anticipate the claimed microorganism since phage A511 is disclosed as being found to contaminate food, dairy products and processing equipments, and is of the same class or family (i.e. a myophage from the family myoviridae) as that of the microorganism claimed and is taught to be effective against the same bacterium, *Listeria monocytogenes*). Consequently, the claimed phage P100 appears to be anticipated by the phage A511, or its recombinant version as disclosed in the prior art references discussed above.

In the alternative, even if the claimed phage P100 is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced phage A511 is likely to possess the same

characteristics of the claimed phage P100 particularly in view of the similar characteristics which they have been shown to share with respect to bacterial host, *Listeria monocytogenes*. Thus the claimed phage P100 would have been obvious to those skilled in the art within the meaning of USC 103(a).

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the prior art references, especially in the absence of evidence (i.e. a comparative data) to the contrary.

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 49-66 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al (US 5,006,347; [A]) in view of Loessner & Busse (1990; [U]), or Loessner et al (1996; IDS).

Claims are drawn to **a method of controlling *Listeria* contamination** in a food product, on food processing equipment, or on food storage containers comprising **applying lytic phage P100** (ATCC patent deposit designation No. PTA 4383) to a food product or food processing equipment in an amount sufficient to reduce the amount of *Listeria*; wherein said P100 phage is applied alone, or in combination with **phage A511** (ATCC patent deposit designation No. PTA 4608), or **at least one agent** as recited in instant claims 51 or 61 (see detailed recitation of instant claims 49-66 and 69).

Day et al [A] disclose a method for retarding or controlling bacterial growth in cheese and use of bacteriophages for controlling unwanted (i.e. bacterial contamination of food) fermentation of food product such as cheese (see abstract, claims, columns 2-4, in particular); wherein the use of lytic phages is generally preferred, as infection results in the rapid destruction of the unwanted bacterial hosts such as Listeria and Clostridium (see column 2, lines 38-41, in particular), wherein the phage containing composition can be in liquid or in lyophilized form (prepared by techniques well known in the art), and may be applied to a food product (in an amount sufficient to cause reduction in bacterial growth; see column 3; 1st and 6th paragraphs, and claims, in particular) in order to reduce the amount of *Listeria*. Day et al also disclose phage preparations or compositions that can comprise of phages specific to several different species of bacterium, including *Listeria* (see column 2, lines 62-66, and claims, in particular). Thus, the reference teaches the use of phages specific for *Listeria* as well as composition suitable for controlling other food contaminating bacteria, such as Clostridium.

However, a method of controlling *Listeria* contamination in a food product, on food processing equipment, or on food storage containers comprising applying (a composition comprising) lytic phage **P100** alone, or in combination with another lytic phage **A511**, though broadly suggested, is not explicitly taught by the invention of Day et al.

The teachings of Loessner & Busse (1990; [U]), and Loessner et al (1996; IDS) are discussed above, and are further relied upon in the same manner herein. Briefly, the prior art references disclose a composition comprising lytic phage A511 in order to aid in the control (by lysis) of the contaminating bacteria, *Listeria monocytogenes* in or on a food product which is substantially identical in the relevant characteristics such as virulent or lytic phenotype, to the claimed phage, and a host range that includes the commonly found bacterial contaminant, *Listeria monocytogenes*.

Given the detailed disclosure of the method for controlling *Listeria* contamination in or on food products such as cheese (using compositions comprising bacteriophages against *Listeria* and/or other bacterial contaminants) by the invention of Day et al, the application of a bacteriophage composition comprising lytic phage A511, would have been obvious to a person ordinary skill in the microbial and food safety art, alone as well as in combination with other type of lytic phage, or further comprising antibacterial agent such as a disinfectant, or an antibiotic for the expected benefit of protecting the public against potential food contaminantion.

One of ordinary skill in the microbial and food safety art would have been motivated at the time of invention to modify in the process of using a phage composition

taught by Day et al by using an effective composition comprising bacteriophage A511 to control *Listeria* contamination in or on food products, as well as on food processing equipments, or on food storage containers, as explicitly suggested by the teachings of Loessner & Busse (see page 1912, in particular) and Loessner et al (for food safety, see page 1133, in particular) for the expected benefit of protecting the public against potential food contaminantion with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103(a).

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made.

As per MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

As per MPEP 2144.06, In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Satyendra K. Singh
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PRIMARY EXAMINER